REMARKS

Claims 1-29 are pending in the present application.

Claims 1-29 have been rejected.

Claims 1-4, 11-14, 21-24 and 28-29 have been amended.

Claims 1-29 remain in the case.

Reconsideration of Claims 1-29, as amended, is respectfully requested.

Amendment to the Specification

The specification has been amended to reflect the fact that a related patent application United States Patent Application Serial No. 09/641,982 has been issued as United States Patent No. 6,666,830 on December 23, 2003.

35 U.S.C. § 102(b) Anticipation

In Paragraph 2 on Pages 2-3 of the December 10, 2003 Office Action, the Examiner rejected Claims 1-2, 4, 6, 11-12, 14 and 16 under 35 U.S.C. § 102 (b) as being anticipated by United States Patent No. 5,123,425 to *Shannon, Jr. et al.* (hereafter "*Shannon*").

The Examiner stated "In regards to claims 1 & 11, Shannon discloses an apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein

said physiological process is terminated before cessation of breathing occurs said apparatus comprising at least one microphone (24 and supporting text) which detects breathing sounds and which generates signals representative of such; a controller (20) coupled to the microphone capable of receiving such breathing sound signals and identifying signals indicative of the onset of said physiological process / (e.g. a partially occluded airway) event before cessation of breathing occurs and capable of generating an alarm signal (col.3 lines 25-50), and a stimulus generator (26 & 28 and supporting text) capable of receiving such alarm signals creating a stimulus and is fully capable of cause said person to move said person's head backwards to terminate said physiological process before cessation of breathing occurs. (note the abstract last full sentence namely the phrase genioglossus and related muscles. Genioglossus muscles are the muscles that control the tongue and "related muscles" are viewed as any other muscles that could be stimulated that are related to the genioglossus muscles that can also be stimulated to the same effect, clearance of the airway thus including those muscles that would tilt back a patient's head & cause the tongue to clear the airway." (December 10, 2003 Office Action, Paragraph 2, Pages 2-3).

The Applicants respectfully traverse the Examiner's assertion that the *Shannon* reference discloses an apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing

occurs. The *Shannon* reference does not disclose these features. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event.

The Applicants also respectfully traverse the Examiner's assertion that the *Shannon* apparatus is capable of identifying signals that indicate "the onset of obstructive sleep apnea / a partially occluded airway event." The Applicants' invention is capable of identifying the "onset" (i.e., the beginning) of an obstructive sleep apnea event before the obstructive sleep apnea event (i.e., cessation of breathing) actually occurs. The *Shannon* apparatus is not able to do this. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event. Further, the *Shannon* reference does not mention "a partially occluded airway event." There is nothing in *Shannon* that suggests or event hints at "a partially occluded airway event" that occurs at the onset of an obstructive sleep apnea event.

The Applicants' invention terminates a physiological process that causes cessation of breathing due to an obstructive sleep apnea event before cessation of breathing occurs by (1) detecting breathing sounds within an airway of a person, and (2) generating signals that are representative of the breathing sounds, and (3) identifying within the signals at least one signal pattern that is associated with a breathing pattern of the person that occurs at the onset of the physiological process before cessation of breathing occurs, and (4) applying a stimulus to the neck muscles of a person to cause the person to move the neck muscles to cause the person's head to move backwards to restore normal breathing before cessation of breathing occurs.

To more particularly claim their invention, the Applicants have amended Claims 1-4, 11-14, 21-24 and 28-29 to claim an apparatus that applies a stimulus to the neck muscles of a person. The *Shannon* apparatus does not teach the concept of detecting the onset of an obstructive sleep apnea event before cessation of breathing occurs. The *Shannon* apparatus also does not teach the concept of stimulating the neck muscles of a person to restore normal breathing before cessation of breathing occurs. Therefore, the Applicants respectfully submit that the amended claims of the patent application are not anticipated by *Shannon*.

The *Shannon* reference shows that the electrodes 26 and 28 are located at the front of collar 10. (*Shannon*, Figures 1, 4, 5). Electrodes 26 and 28 are each "fixed to main substrate 12 such that it will be properly located to stimulate the genioglossus and related muscle groups when collar 10 is in position." (Shannon, Column 3, Lines 43-48). In contrast, the electrodes 500d of the present invention are located at the back of collar 145 where they are placed adjacent to the neck muscles of the person who is wearing collar 145. (Specification, Figure 5). This is because *Shannon* is attempting to stimulate the genioglossus (and the very small muscles that control the tongue) that are located in front of the vertebrae of the neck. The present invention is attempting to stimulate the large skeletal muscles in the neck behind the vertebrae of the neck.

The genioglossus is the muscle of the tongue. To open an occluded pharyngeal airway it is desirable to cause the tongue to extend forward. However, the tongue is only one contributor to an airway closure and other tissues unrelated to the tongue may also contribute to airway closure.

The classic first step of Cardio-Pulmonary Resuscitation (CPR) is to tip up the chin of a victim in respiratory arrest to mechanically flex the head backwards. This action results in the physical defeat of the forces of surface tension that cause adhesion between the tongue and the tissue at the back of the pharynx.

Insertion of a tube that stents the airway open, or forceful tipping of the head backwards are the only certain ways to open the airway. Pulsing electrical energy transcutaneously through the tissues in the front of the neck does not assure airway opening. In fact, electrically stimulating the afferent nerves that control the tongue might actually cause the tongue to retract and thus further block the airway.

Grays Anatomy describes the genioglossus and its four related muscles. These five muscles are referred to as the Lingual Region muscles. (*Grays Anatomy*, Centennial Edition, Bounty Books, New York, 1977, pp. 323 et seq.). These muscles are related because they share one point of common attachment. The genioglossus is also known as the genio-hyo-glossus because it attaches to the jaw, the hyoid bone, and the tongue. Figure 204 on Page 323 shows clearly that these muscles are located at the anterior (front) of the neck and that they have no effect on the vertebrae of the neck. That is, they do not pull the head backwards and they do not contribute to the airway opening function which is related to the backward movement of the head. The cited portions of *Grays Anatomy* are being concurrently submitted with this Amendment.

The neck muscles that control the backward movement of the head as opposed to the movement of the tongue are massive. They are arranged in a thick sheath that is posterior (behind) the cervical vertebrae. (*Grays Anatomy*, Figure 201 on Page 316; Figure 202 on Page 318). The cited portions of *Grays Anatomy* are being concurrently submitted with this Amendment. The *Shannon* apparatus is trying to move the tongue. The Applicants' apparatus is trying to move the head backwards by stimulating the large skeletal neck muscles that run up from the shoulder.

The electrodes 26 and 28 of *Shannon* are located on the neck anterior to (in front of) the cervical vertebrae. The electrodes 26 and 28 of *Shannon* are located at a significant distance from the muscles that run up the back of the neck. The skeletal muscles that control head movement that are closest to the electrodes 26 and 28 of *Shannon* are the rectus capitis group. The muscles in the rectus capitis group have upper points of attachment that are anterior to (in front of) the cervical vertebrae and, if electrically stimulated, would pull the head forward closing the airway.

Therefore, the Applicants respectfully submit that the Examiner's statement is wrong that the *Shannon* apparatus is "fully capable of causing said person to move said person's head backwards to terminate said physiological process before cessation of breathing occurs." (December 10, 2003 Office Action, Page 3, Lines 21-23). The Examiner correctly stated that "Genioglossus muscles are the muscles that control the tongue . . . ." (December 10, 2003 Office Action, Page 3, Lines 24-25). However, the Applicants respectfully submit that the remainder of the Examiner's statement is wrong that expresses the view that " 'related muscles' are viewed as any other muscle

that could be stimulated that are related to the genioglossus muscles that can also be stimulated to the same effect, clearance of the airway thus including those muscles that would tilt back a patient's head & cause the tongue to clear the airway." (December 10, 2003 Office Action, Page 2, Line 25 to Page 3, Line 4). The Applicants respectfully submit that the term "related muscles" as used by *Shannon* can not be extended to muscles that the *Shannon* apparatus is not capable of stimulating. Therefore, the Applicants respectfully submit that the amended claims of the patent application are not anticipated by *Shannon*.

With regard to the meaning of the language used in the *Shannon* reference it is clear that *Shannon* uses the word "onset" to mean the beginning of an actual apnea event when breathing ceases. For example, the output of the *Shannon* sensor "is conditioned and interpreted, and used to determine whenever an apnea event is initiated." (*Shannon*, Column 2, Lines 42-44) (Emphasis added). That an "apnea event" requires the "cessation of breathing" may be seen from the language of Claim 1 of *Shannon*: "An apparatus for treating obstruction of an upper air passageway of a patient . . . . " (Emphasis added).

The *Shannon* reference does not disclose the concept of detecting the onset of an apnea event before cessation of breathing occurs. Like a number of prior art systems *Shannon* is capable of detecting an apnea event by determining the presence or absence of breathing. *Shannon* does not indicate the existence of an apnea event if breathing is present. "Sensor 24 is used to determine the onset of an apnea episode. In the preferred embodiment, this is a microphone or motion sensor which

generates an electrical signal corresponding to the presence of breath or snoring sounds." (Emphasis added) (*Shannon*, Column 3, Lines 25-29). The electronic circuit 200 of *Shannon* activates a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any "presence of breath or snoring sounds." This shows that in *Shannon* the onset of an apnea event begins when cessation of breathing occurs. *Shannon* does not analyze breath sounds that are associated with an onset of an apnea event before cessation of breathing occurs. *Shannon* does not detect a signal that indicates that an apnea event will occur.

The Examiner stated that "At the outset the examiner notes that applicant points to no empirical differences in structure between the prior art device and the instantly claimed invention." (December 10, 2003 Office Action, Page 8). The Applicants respectfully traverse this assertion of the Examiner. First, the Applicant has pointed out that the electrodes 26 and 28 of Shannon are located on the front of collar 10 and are located adjacent to the genioglossus group of muscles. The electrodes 500d of the present invention are located at the back of collar 145 where they are placed adjacent to the neck muscles of the person who is wearing collar 145. This shows a difference in structure between the prior art and the Applicants' apparatus.

Second, in the Applicants's Amendment dated January 13, 2003, the Applicants pointed out that the *Shannon* reference comprises an electronic circuit 200 that activated a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any "presence of breath or snoring sounds." *Shannon* sends a signal to an integrator 206 to

create a "level representing the integrated sensor signal." (*Shannon*, Column 4, Lines 35-36). This "level" is compared to a threshold value set by threshold adjust 216. "This ensures that whenever the integrated circuit levels exceeds the threshold set by threshold adjust 215, a signal is set to on-time timer 208 which initiates a ramp generator 209 for the duration as set by trigger adjust 212." (*Shannon*, Column 4, Lines 38-42). The "levels" that are created and compared to a preset threshold value in the *Shannon* device are not equivalent to the signal patterns that are generated and used in the Applicants' invention.

This description of the *Shannon* electronic circuit 200 shows that (1) the *Shannon* device is structurally different from the Applicants' invention, and (2) the *Shannon* device is not capable of detecting the existence of a partially occluded airway or performing the functions of the Applicant's invention. *Shannon* does not disclose how the threshold adjust 216 obtains a value of threshold. There is nothing in *Shannon* that teaches or suggests that the *Shannon* threshold is anything other than a "breathing" versus "not breathing" threshold. The Applicants respectfully submit that it is not possible to use the *Shannon* device to perform the functions of the Applicants' invention. If the airway of a person was partially occluded, the threshold detection circuit of the *Shannon* device could not detect the partial occlusion.

The Examiner stated that "Applicant points to no structure in his invention that flows as a distinction from the device of the prior art." (December 10, 2003 Office Action, Page 8). The Applicants respectfully traverse this assertion of the Examiner for the reasons set forth above.

The location of electrodes 26 and 28 of Shannon differ from the location of electrodes 500d of the present invention for the reasons previously given. Further, Claim 1 claims a controller that is capable of identifying "at least one signal pattern" that is associated with a breathing pattern of a person that occurs at the onset of a physiological process that, unless terminated, causes cessation of breathing to occur due to an obstructive sleep apnea event. The *Shannon* device is not capable of identifying such signal patterns. The *Shannon* device does not have any hardware that has the capability of the controller of the Applicants' invention.

The Examiner also stated that "The there is no teaching in the prior art that the airway must be fully obstructed before it will act upon ameliorating an apneic event." (December 10, 2003 Office Action, Page 8). The Applicants respectfully traverse this statement of the Examiner. The portions of the *Shannon* reference cited above make it clear that *Shannon* is only capable of detecting cessation of breathing. There are no portions of *Shannon* that suggest otherwise. *Shannon* does not detect and is not capable of detecting a partial obstruction of an airway.

For the reasons set forth above, Applicants respectfully submit that amended Claim 1 contains unique and novel limitations and that amended Claim 1 is not anticipated by the *Shannon* reference. Applicants also respectfully submit that Claim 11, Claim 21, Claim 28 and Claim 29 also contain unique and novel limitations and that Claim 11, Claim 21, Claim 28 and Claim 29 are not anticipated by the *Shannon* reference. Claims 2 through 10 depend from and contain all the unique and novel limitations contained in amended Claim 1. Claims 12 through 20 depend from and

contain all the unique and novel limitations contained in amended Claim 11. Claims 22 through 27 depend from and contain all the unique and novel limitations contained in amended Claim 21. Therefore, Claims 1-29, as amended, are not anticipated by the *Shannon* reference.

The Applicants respectfully request that the rejection of Claims 1-2, 4, 6, 11-12, 14 and 16 under 35 U.S.C. §102(b) as anticipated by the *Shannon* reference be withdrawn and that Claims 1-29, as amended, be passed to issue.

35 U.S.C. § 103(a) Obviousness

In Paragraph 4 on Page 4 of the December 10, 2003 Office Action, the Examiner rejected Claims 7-8, 10, 17-18, 20-22 and 24-29 under 35 U.S.C. § 103 (a) as being obvious in view of *Shannon*.

In Paragraph 5 on Page 5 of the December 10, 2003 Office Action, the Examiner rejected Claims 9 and 19 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 5,058,600 to *Schechter et al.* (hereafter "*Schechter*").

In Paragraph 6 on Pages 5-6 of the December 10, 2003 Office Action, the Examiner rejected Claims 3 and 13 and 23 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 5,652,566 to *Lambert*.

In Paragraph 7 on Pages 6-7 of the December 10, 2003 Office Action, the Examiner rejected Claims 5 and 15 under 35 U.S.C. § 103 (a) as being unpatentable over *Shannon* in view of United States Patent No. 6,011,477 to *Teodorescu et al.* (hereafter "*Teodorescu*").

The Applicants respectfully traverse (1) the Examiner's rejection of Claims 7-8, Claim 10, Claims 17-18, Claims 20-22 and Claims 24-29 as being obvious in view of *Shannon*, (2) the Examiner's rejection of Claim 9 and Claim 19 as being obvious in view of *Shannon* and *Schechter*; (3) the Examiner's rejection of Claim 3, Claim 13 and Claim 23 as being obvious in view of *Shannon* and *Lambert*; and (4) the Examiner's rejection of Claim 5 and Claim 15 as being obvious in view of *Shannon* and *Teodorescu*. The Applicants respectfully request the Examiner to withdraw the rejections of the above referenced claims in view of the Applicants' amendments of Claims 1-4, 11-14, 21-24 and 28-29 and the Applicants' remarks concerning the prior art references.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re*

Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness with respect to the Applicants' invention. The Applicants direct the Examiner's attention to amended Claim 1 which shows novel and unique features:

1. (Currently amended) An apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs, wherein the apparatus comprises:

at least one microphone capable of being acoustically associated with said person, said microphone capable of detecting breathing sounds within said airway of said person and capable of generating signals representative of said breathing sounds;

a controller coupled to said at least one microphone and capable of receiving said signals, said controller capable of identifying within said signals at least one signal pattern that is associated with a breathing pattern of said person that occurs at the onset of, before cessation of breathing occurs, and capable of generating an alarm signal in response thereto; and

a stimulus generator coupled to said controller, said stimulus generator capable of receiving said alarm signal from said controller, and in response thereto, creating a stimulus to said person's neck muscles to cause said person to move said person's neck muscles to move said person's head backwards to terminate said physiological process before cessation of breathing occurs. (Emphasis added).

The Applicants reiterate the arguments that the Applicants have previously made with respect to the *Shannon* reference. There is no teaching, suggestion or even a hint in the *Shannon* reference concerning the Applicants' novel and unique concepts of (1) creating a stimulus to said person's neck muscles to cause said person to move said person's neck muscles to move said person's head backwards to terminate said physiological process before cessation of breathing occurs, and (2) terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of the airway due to an obstructive sleep apnea event, wherein the physiological process is terminated before cessation of breathing occurs. A teaching or suggestion to make the Applicants' invention and a reasonable expectation of success is not found

in the *Shannon* reference (or in any other prior art reference). Therefore, the Applicants' invention is not *prima facie* obvious in view of the *Shannon* reference.

The Applicants respectfully request the Examiner to withdraw the obviousness rejections of the Claims 7-8, 10, 17-18, 20-22 and 24-29 in view of the Applicants' amendments of Claims 1-4, 11-14, 21-24 and 28-29 and the Applicants' remarks concerning the prior art references.

The Examiner has stated that "In regard to claims 9 & 19, Shannon substantially discloses the instant application's claimed invention to include the capability of detecting a breathing signal associated with the onset of an obstructive sleep apnea event, but does not explicitly disclose using software with Fast Fourier Transform (FFT) analysis. However, Schechter discloses such (Note abstract statement that acoustic signals are processed using FFT). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schechter and used them with the device of Shannon. The suggestion/motivation for doing so would have been to effectively process the acoustical data for diagnostic analysis. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention." (December 10, 2003 Office Action, Page 5). The Applicants respectfully traverse the Examiner's assertion that *Shannon* substantially discloses the Applicants' claimed invention. In particular, the Applicants respectfully traverse the Examiner's assertion that *Shannon* teaches all the limitations of Claims 9 and 19 except that the software analyzes the signals using a

Fast Fourier Transform analysis. The Applicants also respectfully traverse the Examiner's assertion that it would have been obvious to combine the *Schechter* reference with the *Shannon* reference.

Claim 9 depends from amended Claim 8 (which, in turn, depends from amended Claim 1). Claim 19 depends from amended Claim18 (which, in turn, depends from amended Claim 11). As previously described, *Shannon* (1) does not analyze breath sounds that are associated with an onset of an apnea event before cessation of breathing occurs, and (2) does not create a stimulus to a person's neck muscles to cause the person to move the person's neck muscles to move the person's head backwards to terminate a physiological process leading to apnea before cessation of breathing occurs. *Schechter* discloses an expert diagnostic system that is designed to detect pathological obstructions and not temporary obstructions such as an obstructive apnea event. Even if *Schechter* apparatus could detect an obstructive apnea event it would not detect the obstructive apnea event until after the obstructive apnea event had occurred (i.e., until after the cessation of breathing had occurred).

The *Schechter* reference does not disclose a signal analysis template for detecting an obstructive apnea event or for detecting an onset of an obstructive apnea event. That is, there is no signal analysis mechanism in *Schechter* for detecting an obstructive apnea event. Therefore, unlike the Applicants' invention, the *Schechter* system will identify breath sounds that are associated with an "onset" of an obstructive apnea event as "normal" breath sounds. *Schechter* does not disclose,

suggest, or even hint at the concept of using of spectral analysis techniques to detect an obstructive apnea event or to detect an onset of an obstructive apnea event.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Schechter* reference. "When a rejection depends on a combination of prior art references, there must be some teaching, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). "It is insufficient to establish obviousness that the separate elements of an invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the references." *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). The Applicants respectfully submit that there exists no teaching, suggestion or motivation in the prior art to combine the teachings of the *Shannon* reference and the teachings of the *Schechter* reference.

When two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Schechter* reference, the combination of the *Shannon* reference and the *Schechter* reference would not teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Schechter* reference does not teach, suggest, or even hint at the Applicants' concept of using of spectral analysis techniques to detect an obstructive apnea event or to detect an onset of an obstructive apnea event. The Applicants respectfully request the Examiner to withdraw the

obviousness rejections of the Claims 9 and 19 in view of the Applicants' amendments of Claims 1-4, 11-14, 21-24 and 28-29 and the Applicants' remarks concerning the prior art references.

With respect to the rejection of Claim 3, Claim 13 and Claim 23, the Examiner has stated that "[I]t would have been obvious to one of ordinary skill in the art to have taken the features of Lambert and used them with the device of Shannon. The suggestion/motivation for doing so would have been to provide additional/redundant alarm systems, insuring the user is stimulated." (December 10, 2003 Office Action, Pages 5-6). The Applicants respectfully traverse the Examiner's assertion that it would be obvious to combine the teaching of *Shannon* with the teachings of *Lambert*.

Claim 3 depends from amended Claim 1. Claim 13 depends from amended Claim 11. Claim 23 depends from amended Claim 21. Each of the amended independent claims contain a claim limitation restricting the detection of an onset of an obstructive apnea event to a time "before cessation of breathing occurs." Each of the amended independent claims also contain a claim limitation that creates a stimulus to a person's neck muscles to cause the person to move the person's neck muscles to move the person's head backwards to terminate a physiological process leading to apnea before cessation of breathing occurs. These elements are not present in *Shannon* or in *Lambert*.

Further, the reliability that is provided by the redundant alarm system of *Lambert* is <u>not</u> needed for the Applicants' invention. *Lambert* states that "Reliability is a critical requirement for effective alarm systems. For example, in a hospital, a patient's life often depends on the effective

operation of a medical monitor alarm." (*Lambert*, Col. 1, Lines 1-13). The Applicants' invention is not a life saving monitor because people do not die from an episode of obstructive apnea. They always re-open an obstructed airway with the body's gasping reflex. Therefore, the level of reliability provided by the *Lambert* system is not required.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Lambert* reference. Further, when two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Lambert* reference, the combination of the *Shannon* reference and the *Lambert* reference would not teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Shannon* reference does not teach, suggest, or even hint at the Applicants' concept of detecting an apnea event "before cessation of breathing occurs" or the Applicants' concept of creating a stimulus to a person's neck muscles to cause the person to move the person's neck muscles to move the person's head backwards to terminate a physiological process leading to apnea before cessation of breathing occurs.

The Applicants respectfully request the Examiner to withdraw the obviousness rejections of the Claim 3, Claim 13 and Claim 23 in view of the Applicants' amendments of Claims 1-4, 11-14, 21-24 and 28-29 and the Applicants' remarks concerning the prior art references.

With respect to the rejection of Claim 5 and Claim 15, the Examiner has stated that "At the time the instant application's invention was made, it would have been obvious to one of

ordinary skill in the art to have taken the features of Teodorescu and used them with the device of Shannon. The suggestion/motivation for doing so would have been to give the user more range/freedom of movement during use of the device. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention." (December 10, 2003 Office Action, Pages 6-7).

Claim 5 depends from amended Claim 1. Claim 15 depends from amended Claim 11. Each of the amended independent claims contain a claim limitation restricting the detection of an onset of an obstructive apnea event to a time "before cessation of breathing occurs." Each of the amended independent claims also contain a claim limitation that creates a stimulus to a person's neck muscles to cause the person to move the person's neck muscles to move the person's head backwards to terminate a physiological process leading to apnea before cessation of breathing occurs. These elements are not present in *Shannon* or in *Teodorescu*.

Further, the supposed suggestion/motivation for combining the *Shannon* reference and the *Teodorescu* reference was said to be to give the user more range/freedom of movement during use of the device. But the user of the device is asleep during the time that the device is being used. The user is not moving in a manner that requires "more range/freedom of movement."

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Teodorescu* reference. Further, when two references are combined the combination of the references must teach or suggest all the claim limitations. In the

present case, even if the *Shannon* reference were combined with the *Teodorescu* reference, the combination of the *Shannon* reference and the *Teodorescu* reference would not teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Shannon* reference does not teach, suggest, or even hint at the Applicants' concept of detecting an apnea event "before cessation of breathing occurs" or the Applicants' concept of creating a stimulus to a person's neck muscles to cause the person to move the person's neck muscles to move the person's head backwards to terminate a physiological process leading to apnea before cessation of breathing occurs.

The Applicants respectfully request the Examiner to withdraw the obviousness rejections of Claim 5 and Claim 15 in view of the Applicants' amendments of Claims 1-4, 11-14, 21-24 and 28-29 and the Applicants' remarks concerning the prior art references.

The Applicants respectfully submit that Claims 1-29, as amended, are all patentable over the *Shannon* and the *Schechter* reference and the *Lambert* reference and the *Teodorescu* reference whether taken individually or in combination. The Applicants respectfully request that the rejection of Claims 1-29 be withdrawn and that Claims 1-29, as amended, be passed to issue.

The Applicants deny any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. The Applicants reserve the right to submit further arguments in support of their above stated position as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY

For the reasons given above, the Applicants respectfully request reconsideration and allowance of pending claims and that this Application be passed to issue. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this Application, the Applicants respectfully invite the Examiner to contact the undersigned at the telephone number indicated below or at ***wmunck@davismunck.com***.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

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ANATOMY,

DESCRIPTIVE AND SURGICAL.

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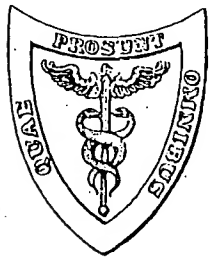

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The muscles contained in each of these groups are the following:

1. *Superficial Region.*
   - Platysma myoides.
   - Sterno-cleido-mastoid.

Infra-hyoid Region.

2. *Depressors of the Os hyoides and Larynx.*
   - Sterno-hyoid.
   - Sterno-thyroid.
   - Thyro-hyoid.
   - Omo-hyoid.

Supra-hyoid Region.

3. *Elevators of the Os hyoides and Larynx.*
   - Digastric.
   - Stylo-hyoid.
   - Mylo-hyoid.
   - Genio-hyoid.

Lingual Region.

4. *Muscles of the Tongue.*
   - Genio-hyo-glossus.
   - Hyo-glossus.
   - Chondro-glossus.
   - Stylo-glossus.
   - Palato-glossus.

5. *Muscles of the Pharynx.*
   - Inferior constrictor.
   - Middle constrictor.
   - Superior constrictor.
   - Stylo-pharyngeus.
   - Palato-pharyngeus.

6. *Muscles of the Soft Palate.*
   - Levator palati.
   - Tensor palati.
   - Azygos uvulæ.
   - Palato-glossus.
   - Palato-pharyngeus.
   - Salpingo-pharyngeus.

7. *Muscles of the Anterior Vertebral Region.*
   - Rectus capitis anticus major.
   - Rectus capitis anticus minor.
   - Rectus capitis lateralis.
   - Longus colli.

8. *Muscles of the Lateral Vertebral Region.*
   - Scalenus anticus.
   - Scalenus medius.
   - Scalenus posticus.

9. *Muscles of the Larynx.*
   - Included in the description of the Larynx.

1. Superficial Cervical Region.

Platysma myoides. Sterno-cleido-mastoid.

Dissection.—A block having been placed at the back of the neck, and the face turned to the side opposite that to be dissected, so as to place the parts upon the stretch, make two transverse incisions: one from the chin, along the margin of the lower jaw, to the mastoid process, and the other along the upper border of the clavicle. Connect these by an oblique incision made in the course of the Sterno-mastoid muscle, from the mastoid process to the sternum; the two flaps of integument having been removed in the direction shown in Fig. 194, the superficial fascia will be exposed.

The **Superficial Cervical Fascia** is a thin, aponeurotic lamina which is hardly demonstrable as a separate membrane. Beneath it is found the Platysma myoides muscle.

The **Platysma myoides** (Fig. 195) is a broad, thin plane of muscular fibres placed immediately beneath the superficial fascia on each side of the neck. It arises by thin, fibrous bands from the fascia covering the upper part of the Pectoral and Deltoid muscles; its fibres pass over the clavicle and proceed obliquely upward and inward along the side of the neck. The anterior fibres interlace, below and behind the symphysis menti, with the fibres of the muscle of the opposite side; the posterior fibres pass over the lower jaw, some of them being attached to the bone below the external oblique line, others passing on to be inserted into the skin and subcutaneous tissue of the lower part of the face, many of these fibres blending with the muscles about the angle and lower part of the mouth. Sometimes fibres can be traced to the Zygomatic muscles or to the margin of the Orbicularis oris. Beneath the Platysma the external jugular vein may be seen descending from the angle of the jaw to the clavicle.

Surgical Anatomy.—It is essential to remember the direction of the fibres of the Platysma in connection with the operation of bleeding from the external jugular vein; for if the point of the lancet is introduced in the direction of the muscular fibres, the orifice made will be filled up by the contraction of the muscle, and blood will not flow; but if the incision is made across the course of the fibres, they will retract and expose the orifice in the vein, and so allow the flow of blood.

Relations.—By its *external surface*, with the integument, to which it is united more closely below than above; by its *internal surface*, with the Pectoralis major and Deltoid, and with the clavicle. In the *neck*, with the external and anterior jugular veins, the deep cervical fascia, the superficial branches of the cervical plexus, the Sterno-mastoid, Sterno-hyoid, Omo-hyoid, and Digastric muscles; behind the Sterno-mastoid muscle it covers in the posterior triangle of the neck. On the *face* it is in relation with the parotid gland, the facial artery and vein, and the Masseter and Buccinator muscles.

Action.—The Platysma myoides produces a slight wrinkling of the surface of the skin of the neck, in an oblique direction, when the entire muscle is brought into action. Its anterior portion, the thickest part of the muscle, depresses the lower jaw; it also serves to draw down the lower lip and angle of the mouth on each side, being one of the chief agents in the expression of melancholy.

The Deep cervical fascia lies under cover of the Platysma myoides muscle and constitutes a complete investment for the neck. It also forms a sheath for the carotid vessels, and, in addition, is prolonged deeply in the shape of certain processes or lamellæ, which come into close relation with the structures situated in front of the vertebral column.

The investing portion of the fascia is attached behind to the ligamentum nuchæ and to the spine of the seventh cervical vertebra. Along this line it splits to enclose the Trapezius muscle, at the anterior border of which the two enclosing lamellæ unite and form a strong membrane, which extends forward so as to roof in the posterior triangle of the neck. Along the hinder edge of the Sterno-mastoid this membrane again divides to enclose this muscle, at the anterior edge of which it once more forms a single lamella, which roofs in the anterior triangle of the neck, and, reaching forward to the middle line, is continuous with the corresponding part from the opposite side of the neck. In the middle line of the neck it is attached to the symphysis menti and body of the hyoid bone.

Above, the fascia is attached to the superior curved line of the occiput, to the mastoid process of the temporal, and to the whole length of the body of the jaw. Opposite the angle of the jaw the fascia is very strong, and binds the anterior edge of the Sterno-mastoid firmly to that bone. Between the jaw and the mastoid process it ensheaths the parotid gland—the layer which covers the gland extending upward under the name of the parotid fascia to be fixed to the zygomatic arch. From the layer which passes under the parotid a strong band, *the stylo-mandibular ligament*, reaches from the styloid process to the angle of the jaw.

Below, the fascia is attached to the acromion process, the clavicle, and manubrium sterni. Some little distance above the last, however, it splits into two layers, superficial and deep. The former is attached to the anterior border of the manubrium, the latter to its posterior border and to the interclavicular ligament. Between these two layers is a slit-like interval, the *suprasternal space*, or *space of Burns*. It contains a small quantity of areolar tissue, and sometimes a lymphatic gland; the lower portions of the anterior jugular veins and their transverse connecting branch; and also the sternal heads of the Sterno-mastoid muscles.

The fascia which lines the deep aspect of the Sterno-mastoid gives off certain important processes, viz.: (1) A process to envelop the tendon of the Omo-hyoid, and bind it down to the sternum and first costal cartilage. (2) A strong sheath, the carotid sheath, for the large vessels of the neck, enclosed within which are the carotid artery, internal jugular vein, the vagus, and descendens hypoglossi nerves. (3) The prevertebral fascia, which extends inward behind the carotid vessels, where it assists in forming their sheath, and passes in front of the prevertebral muscles. It thus forms the posterior limit of a fibrous compartment which contains

the larynx and trachea, the thyroid gland, and the pharynx and œsophagus. The prevertebral fascia is fixed above to the base of the skull, while below it is continued into the thorax in front of the Longus colli muscles. Parallel to the carotid vessels and along their inner aspect it gives off a thin lamina, the *bucco-pharyngeal fascia*, which closely invests the constrictor muscles of the pharynx, and is continued forward from the Superior constrictor on to the Buccinator. It is attached to the prevertebral layer by loose connective tissue only, and thus an easily distended space, the *retro-pharyngeal space*, is found between them. This space is limited above by the base of the skull, while below it extends behind the

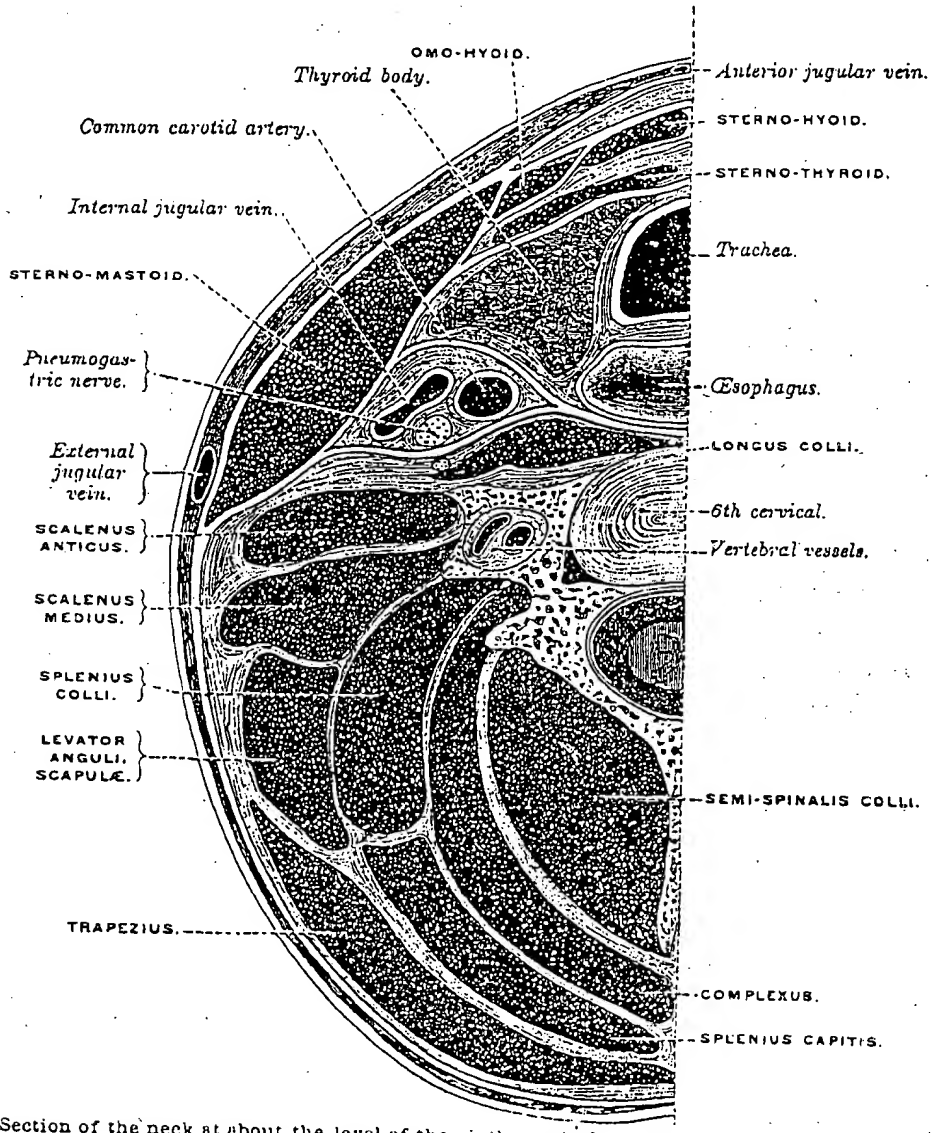

FIG. 201.—Section of the neck at about the level of the sixth cervical vertebra. Showing the arrangement of the deep cervical fascia.

œsophagus into the thorax, where it is continued into the posterior mediastinum. The prevertebral fascia is prolonged downward and outward behind the carotid vessels and in front of the Scaleni muscles, and forms a sheath for the brachial nerves and subclavian vessels in the posterior triangle of the neck, and, continued under the clavicle as the axillary sheath, is attached to the deep surface of the costo-coracoid membrane. Immediately above the clavicle an areolar space exists between the investing layer and the sheath of the subclavian vessels, and in it are found the lower part of the external jugular vein, the descending clavicular nerves, the suprascapular and transversalis colli vessels, and the posterior belly of the

Omo-hyoid muscle. This space extends downward behind the clavicle, and is limited below by the fusion of the costo-coracoid membrane with the anterior wall of the axillary sheath. (4) The pre-tracheal fascia, which extends inward in front of the carotid vessels, and assists in forming the carotid sheath. It is further continued behind the depressor muscles of the hyoid bone, and, after enveloping the thyroid body, is prolonged in front of the trachea to meet the corresponding layer of the opposite side. Above, it is fixed to the hyoid bone, while below it is carried downward in front of the trachea and large vessels at the root of the neck, and ultimately blends with the fibrous pericardium.

Surgical Anatomy.—The cervical fascia is of considerable importance from a surgical point of view. As will be seen from the foregoing description, it may be divided into three layers: (1) A superficial layer; (2) a layer passing in front of the trachea, and forming with the superficial layer a sheath for the depressors of the hyoid bone; (3) a prevertebral layer passing in front of the bodies of the cervical vertebræ, and forming with the second layer a space in which are contained the trachea, œsophagus, etc. The superficial layer forms a complete investment for the neck. It is attached behind to the ligamentum nuchæ and the spine of the seventh cervical vertebra; above it is attached to the external occipital protuberance, to the superior curved line of the occiput, to the mastoid process, to the zygoma and the lower jaw; below it is attached to the manubrium sterni, the clavicle, the acromion process, and the spine of the scapula; in front it blends with the fascia of the opposite side. This layer would oppose the extension of abscesses or new growths toward the surface, and pus forming beneath it would have a tendency to extend laterally. If it is in the posterior triangle, it might extend backward under the Trapezius, forward under the Sterno-mastoid, or downward under the clavicle for some distance, until stopped by the junction of the cervical fascia to the Costo-coracoid membrane. If the pus is contained in the anterior triangle, it might find its way into the anterior mediastinum, being situated in front of the layer of fascia which passes down into the thorax to become continuous with the pericardium; but owing to the lesser density and thickness of the fascia in this situation it more frequently finds its way through it and points above the sternum. The second layer of fascia is connected above with the hyoid bone. It passes down beneath the depressors and in front of the thyroid body and trachea to become continuous with the fibrous layer of the pericardium. Laterally it invests the great vessels of the neck and is connected with the superficial layer beneath the Sterno-mastoid. Pus forming beneath this layer would in all probability find its way into the posterior mediastinum. The third layer (the prevertebral fascia) is connected above to the base of the skull. Pus forming beneath this layer, in cases, for instance, of caries of the bodies of the cervical vertebræ, might extend toward the posterior and lateral part of the neck and point in this situation, or might perforate this layer of fascia and the pharyngeal fascia and point into the pharynx (retro-pharyngeal abscess).

In cases of cut throat the cervical fascia is of considerable importance. When the wound involves only the superficial layer the injury is usually trivial, the only special danger being injury to the external jugular vein, and the only special complication being diffuse cellulitis. But where the second of the two layers has been opened up, important structures may have been injured, which may lead to serious results.

It may be worth while mentioning that in Burns's space is contained the sternal head of origin of the Sterno-mastoid muscle, so that this space is opened in division of this tendon. The anterior jugular vein is also contained in the same space.

The **Sterno-mastoid** or **Sterno-cleido-mastoid** (Fig. 202) is a large, thick muscle, which passes obliquely across the side of the neck, being enclosed between the two layers of the deep cervical fascia. It is thick and narrow at its central part, but is broader and thinner at each extremity. It arises, by two heads, from the sternum and clavicle. The *sternal portion* is a rounded fasciculus, tendinous in front, fleshy behind, which arises from the upper and anterior part of the first piece of the sternum, and is directed upward, outward, and backward. The *clavicular portion* arises from the inner third of the superior border and anterior surface of the clavicle, being composed of fleshy and aponeurotic fibres; it is directed almost vertically upward. These two portions are separated from one another, at their origin, by a triangular cellular interval, but become gradually blended, below the middle of the neck, into a thick, rounded muscle, which is inserted, by a strong tendon, into the outer surface of the mastoid process, from its apex to its superior border, and by a thin aponeurosis into the outer half of the superior curved line of the occipital bone. The Sterno-mastoid varies much in its extent of attachment to the clavicle: in one case the clavicular may be as narrow as the sternal portion; in another, as much as three inches in breadth. When the clavicular

origin is broad, it is occasionally subdivided into numerous slips separated by narrow intervals. More rarely, the corresponding margins of the Sterno-mastoid and Trapezius have been found in contact. In the application of a ligature to the third part of the subclavian artery it will be necessary, where the muscles come close together, to divide a portion of one or of both.

This muscle divides the quadrilateral space at the side of the neck into two triangles, an anterior and a posterior. The boundaries of the *anterior triangle* are, in front, the median line of the neck; above, the lower border of the body of the jaw, and an imaginary line drawn from the angle of the jaw to the mastoid

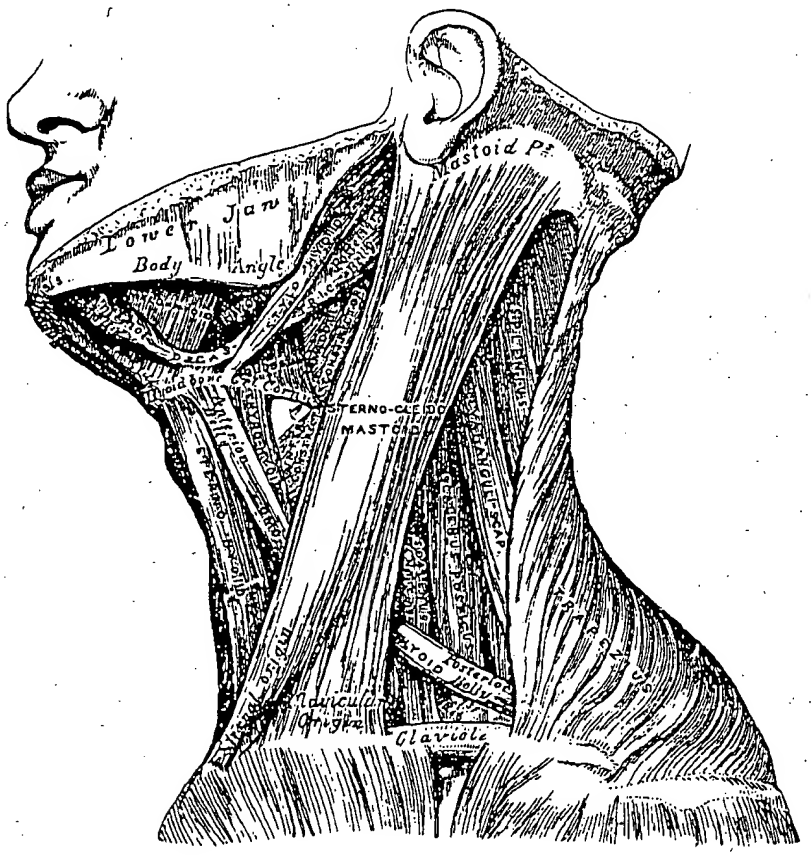

FIG. 202.—Muscles of the neck and boundaries of the triangles.

process; behind, the anterior border of the Sterno-mastoid muscle. The apex of the triangle is at the upper border of the sternum. The boundaries of the *posterior triangle* are, in front, the posterior border of the Sterno-mastoid; below, the middle third of the clavicle; behind, the anterior margin of the Trapezius.[1] The apex corresponds with the meeting of the Sterno-mastoid and Trapezius on the occipital bone.

Relations.—By its *superficial surface*, with the integument and Platysma, from which it is separated by the external jugular vein, the superficial branches of the cervical plexus, and the anterior layer of the deep cervical fascia. By its *deep surface* it is in relation with the Sterno-clavicular articulation; a process of the deep cervical fascia; the Sterno-hyoid, Sterno-thyroid, Omo-hyoid, posterior belly of the Digastric, Levator anguli scapulæ, Splenius and Scaleni muscles; common carotid artery, internal and anterior jugular veins, commencement of the internal and external carotid arteries, the occipital, subclavian, transversalis colli, and suprascapular arteries and veins; the phrenic, pneumogastric, hypoglossal, descendens and communicans hypoglossi nerves; the spinal accessory nerve, which

[1] The anatomy of these triangles will be more exactly described with that of the vessels of the neck.

pierces its upper third; the cervical plexus, parts of the thyroid and parotid glands, and deep lymphatic glands.

Nerves.—The Platysma myoides is supplied by the facial nerve; the Sterno-cleido-mastoid, by the spinal accessory and deep branches of the cervical plexus.

Actions.—When only one Sterno-mastoid muscle acts, it draws the head toward the shoulder of the same side, assisted by the Splenius and the Obliquus capitis inferior of the opposite side. At the same time it rotates the head so as to carry the face toward the opposite side. If the head is fixed, the two muscles assist in elevating the thorax in forced inspiration.

Surface Form.—The anterior edge of the muscle forms a very prominent ridge beneath the skin, which it is important to notice, as it forms a guide to the surgeon in making the necessary incisions for ligature of the common carotid artery and for œsophagotomy.

Surgical Anatomy.—The relations of the sternal and clavicular parts of the Sterno-mastoid should be carefully examined, as the surgeon is sometimes required to divide one or both portions of the muscles in *wry-neck*. One variety of this distortion is produced by spasmodic contraction or rigidity of the Sterno-mastoid; the head being carried down toward the shoulder of the same side, and the face turned to the opposite side and fixed in that position. When there is permanent shortening, subcutaneous division of the muscle is resorted to by some surgeons. This is performed by introducing a tenotomy knife beneath it, close to its origin, and dividing it from behind forward whilst the muscle is put well upon the stretch. There is seldom any difficulty in dividing the sternal portion by making a puncture on the inner side of the tendon, and then pushing a blunt tenotome behind it, and cutting forward. In dividing the clavicular portion care must be taken to avoid wounding the external jugular vein, which runs parallel with the posterior border of the muscle in this situation, or the anterior jugular vein, which crosses beneath it. If the external jugular vein lies near the muscle, it is safer to make the first puncture at the outer side of the tendon, and introduce a blunt tenotome from without inward. Many surgeons prefer dividing the muscle by the open method. An incision is made over either origin of the muscle, the tendon is exposed, a director is passed underneath it, and it is then divided. With care and attention to asepsis this plan of treatment is devoid of risk, and in this way the accidental division of the vessels can be avoided. Some of the fibres of the Sterno-mastoid muscle are occasionally torn during birth, especially in breech presentations; this is accompanied by hemorrhage and formation of a swelling within the substance of the muscle. This by some is believed to be one of the causes of wry-neck, the scar tissue which is formed contracting and shortening the muscle.

2. Infra-hyoid Region (Figs. 202, 203).

Depressors of the Os Hyoides and Larynx.

Sterno-hyoid.	Thyro-hyoid.
Sterno-thyroid.	Omo-hyoid.

Dissection.—The muscles in this region may be exposed by removing the deep fascia from the front of the neck. In order to see the entire extent of the Omo-hyoid it is necessary to divide the Sterno-mastoid at its centre, and turn its ends aside, and to detach the Trapezius from the clavicle and scapula. This, however, should not be done until the Trapezius has been dissected.

The **Sterno-hyoid** is a thin, narrow, ribbon-like muscle, which arises from the inner extremity of the clavicle, the posterior sterno-clavicular ligament, and the upper and posterior part of the first piece of the sternum; passing upward and inward, it is inserted, by short, tendinous fibres, into the lower border of the body of the os hyoides. This muscle is separated, below, from its fellow by a considerable interval; but the two muscles come into contact with one another in the middle of their course, and from this upward lie side by side. It sometimes presents, immediately above its origin, a transverse tendinous intersection, like those in the Rectus abdominis.

Relations.—By its *superficial surface*, below, with the sternum, the sternal end of the clavicle, and the Sterno-mastoid; and above, with the Platysma and deep cervical fascia; by its *deep surface*, with the Sterno-thyroid, Crico-thyroid, and Thyro-hyoid muscles, the thyroid gland, the superior thyroid vessels, the thyroid cartilage, the crico-thyroid and thyro-hyoid membranes.

The **Sterno-thyroid** is situated beneath the preceding muscle, but is shorter and wider than it. It arises from the posterior surface of the first bone of the sternum,

below the origin of the Sterno-hyoid, and from the edge of the cartilage of the first rib, occasionally of the second rib also, and is inserted into the oblique line on the side of the ala of the thyroid cartilage. This muscle is in close contact with its fellow at the lower part of the neck, and is occasionally traversed by a transverse or oblique tendinous intersection, like those in the Rectus abdominis.

Relations.—By its *anterior surface*, with the Sterno-hyoid, Omo-hyoid, and Sterno-mastoid; by its *posterior surface*, from below upward, with the trachea, vena innominata, common carotid (and on the right side the arteria innominata), the thyroid gland and its vessels, and the lower part of the larynx and pharynx. The inferior thyroid vein lies along its inner border, a relation which it is important to remember in the operation of tracheotomy. On the left side the deep surface of the muscle is in relation to the œsophagus.

The **Thyro-hyoid** is a small, quadrilateral muscle appearing like a continuation of the Sterno-thyroid. It arises from the oblique line on the side of the thyroid cartilage, and passes vertically upward to be inserted into the lower border of the body and greater cornu of the hyoid bone.

Relations.—By its *external surface*, with the Sterno-hyoid and Omo-hyoid muscles; by its *internal surface*, with the thyroid cartilage, the thyro-hyoid membrane, and the superior laryngeal vessels and nerve.

The **Omo-hyoid** passes across the side of the neck, from the scapula to the

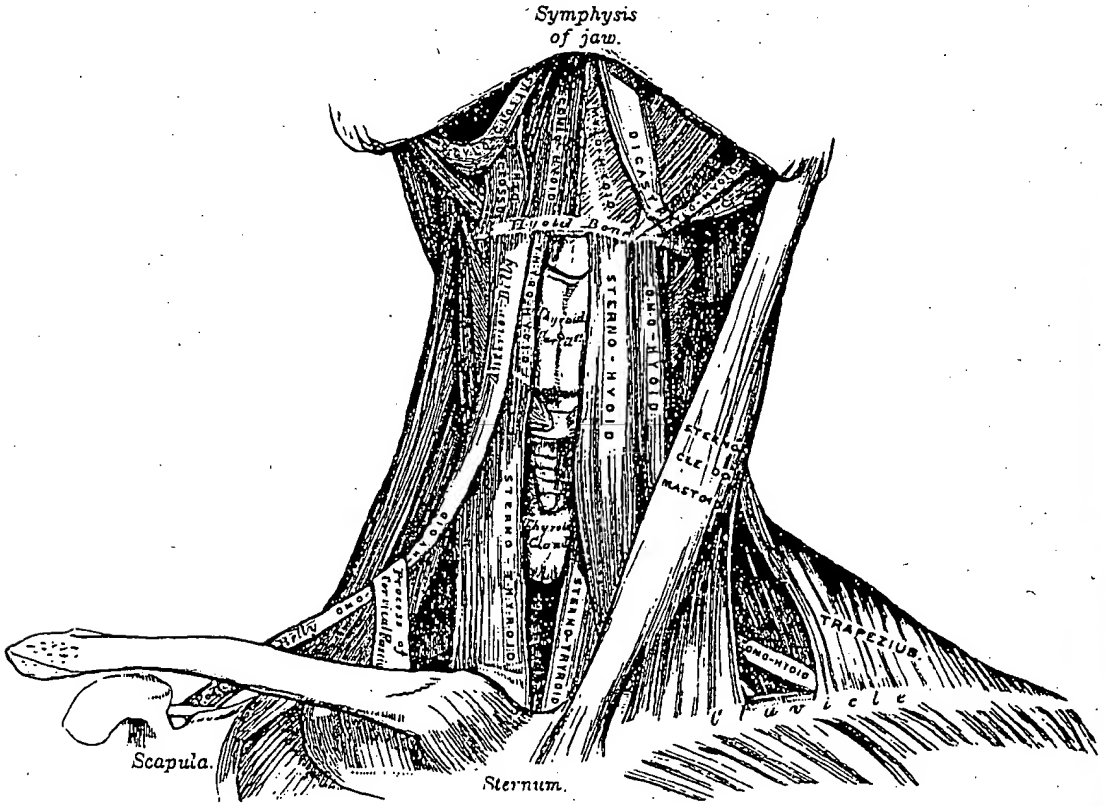

FIG. 203.—Muscles of the neck. Anterior view.

hyoid bone. It consists of two fleshy bellies, united by a central tendon. It arises from the upper border of the scapula, and occasionally from the transverse ligament which crosses the suprascapular notch, its extent of attachment to the scapula varying from a few lines to an inch. From this origin the posterior belly forms a flat, narrow fasciculus, which inclines forward and slightly upward across the lower part of the neck, behind the Sterno-mastoid muscle, where it becomes tendinous; it then changes its direction, forming an obtuse angle, and terminates in the anterior belly, which passes almost vertically upward, close to the outer border of the Sterno-hyoid, to be inserted into the lower border of the body of the

os hyoides, just external to the insertion of the Sterno-hyoid. The central tendon of this muscle, which varies much in length and form, is held in position by a process of the deep cervical fascia, which includes it in a sheath. This process is prolonged down, to be attached to the clavicle and first rib. It is by this means that the angular form of the muscle is maintained.

This muscle subdivides each of the two large triangles at the side of the neck into two smaller triangles; the two posterior ones being the *posterior superior* or *occipital*, and the *posterior inferior* or *subclavian;* the two anterior, the *anterior superior* or *superior carotid*, and the *anterior inferior* or *inferior carotid triangles.*

Relations.—By its *superficial surface*, with the Trapezius, the Sterno-mastoid, deep cervical fascia, Platysma, and integument; by its *deep surface*, with the Scaleni muscles, phrenic nerve, lower cervical nerves, which go to form the brachial plexus, the suprascapular vessels and nerve, sheath of the common carotid artery and internal jugular vein, the Sterno-thyroid and Thyro-hyoid muscles.

Nerves.—The Thyro-hyoid is supplied by the hypoglossal; the other muscles of this group by branches from the loop of communication between the descendens and communicans hypoglossi.

Actions.—These muscles depress the larynx and hyoid bone, after they have been drawn up with the pharynx in the act of deglutition. The Omo-hyoid muscles not only depress the hyoid bone, but carry it backward and to one or the other side. It is concerned especially in prolonged inspiratory efforts; for by tensing the lower part of the cervical fascia it lessens the inward suction of the soft parts, which would otherwise compress the great vessels and the apices of the lungs. The Thyro-hyoid may act as an elevator of the thyroid cartilage when the hyoid bone ascends, drawing upward the thyroid cartilage, behind the os hyoides. The Sterno-thyroid acts as a depressor of the thyroid cartilage.

3. Supra-hyoid Region (Figs. 202, 203).

ELEVATORS OF THE OS HYOIDES—DEPRESSORS OF THE LOWER JAW.

Digastric.	Mylo-hyoid.
Stylo-hyoid.	Genio-hyoid.

Dissection.—To dissect these muscles a block should be placed beneath the back of the neck, and the head drawn backward and retained in that position. On the removal of the deep fascia the muscles are at once exposed.

The **Digastric** consists of two fleshy bellies united by an intermediate, rounded tendon. It is a small muscle, situated below the side of the body of the lower jaw, and extending, in a curved form, from the side of the head to the symphysis of the jaw. The *posterior belly*, longer than the anterior, arises from the digastric groove on the inner side of the mastoid process of the temporal bone, and passes downward, forward, and inward. The *anterior belly* arises from a depression on the inner side of the lower border of the jaw, close to the symphysis, and passes downward and backward. The two bellies terminate in the central tendon which perforates the Stylo-hyoid, and is held in connection with the side of the body and the greater cornu of the hyoid bone by a fibrous loop, lined by a synovial membrane. A broad aponeurotic layer is given off from the tendon of the Digastric on each side, which is attached to the body and great cornu of the hyoid bone: this is termed the *supra-hyoid aponeurosis.* It forms a strong layer of fascia between the anterior portion of the two muscles, and a firm investment for the other muscles of the supra-hyoid region which lie deeper.

The Digastric muscle divides the anterior superior triangle of the neck into two smaller triangles; the upper, or *submaxillary*, being bounded, above, by the lower border of the body of the jaw, and a line drawn from its angle to the mastoid process; below, by the posterior belly of the Digastric and the Stylo-hyoid muscles; in front, by the middle line of the neck and the anterior belly of the Digastric, the lower or *superior carotid triangle* being bounded above by the posterior belly of the Digastric, behind by the Sterno-mastoid, below by the Omo-hyoid.

Relations.—By its *superficial surface* with the mastoid process, the Platysma, Sterno-mastoid, part of the Splenius, Trachelo-mastoid, and Stylo-hyoid muscles, and the parotid gland. By its *deep surface*, the anterior belly lies on the Mylo-hyoid; the posterior belly on the Stylo-glossus, Stylo-pharyngeus, and Hyo-glossus muscles, the external carotid artery and its occipital, lingual, facial, and ascending pharyngeal branches, the internal carotid artery, internal jugular vein, and hypoglossal nerve.

The **Stylo-hyoid** is a small, slender muscle, lying in front of, and above, the posterior belly of the Digastric. It arises from the back and outer surface of the styloid process, near the base; and, passing downward and forward, is inserted into the body of the hyoid bone, just at its junction with the greater cornu, and immediately above the Omo-hyoid. This muscle is perforated, near its insertion, by the tendon of the Digastric.

Relations.—By its *superficial surface* above with the parotid gland and deep cervical fascia; below it is superficial, being situated immediately beneath the deep cervical fascia. By its *deep surface*, with the posterior belly of the Digastric, the external carotid artery, with its lingual and facial branches, the Hyo-glossus muscle, and the hypoglossal nerve.

The Stylo-hyoid Ligament.—In connection with the Stylo-hyoid muscle may be described a ligamentous band, the *Stylo-hyoid ligament*. It is a fibrous cord, often containing a little cartilage in its centre, which continues the styloid process down to the hyoid bone, being attached to the tip of the former and the small cornu of the latter. It is often more or less ossified, and in many animals forms a distinct bone, the *epihyal*.

The anterior belly of the Digastric should be removed, in order to expose the next muscle.

The **Mylo-hyoid** is a flat, triangular muscle, situated immediately beneath the anterior belly of the Digastric, and forming, with its fellow of the opposite side, a muscular floor for the cavity of the mouth. It arises from the whole length of the mylo-hyoid ridge of the lower jaw, extending from the symphysis in front to the last molar tooth behind. The posterior fibres pass inward and slightly downward, to be inserted into the body of the os hyoides. The middle and anterior fibres are inserted into a median fibrous raphé, extending from the symphysis of the lower jaw to the hyoid bone, where they join at an angle with the fibres of the opposite muscle. The median raphé is sometimes wanting; the muscular fibres of the two sides are then directly continuous with one another.

Relations.—By its *cutaneous* or *under surface*, with the Platysma, the anterior belly of the Digastric, the supra-hyoid aponeurosis, the submaxillary gland, submental vessels, and mylo-hyoid vessels and nerve; by its *deep* or *superior surface*, with the Genio-hyoid, part of the Hyo-glossus and Stylo-glossus muscles, the hypoglossal and lingual nerves, the submaxillary ganglion, the sublingual gland, the deep portion of the submaxillary gland, and Wharton's duct; the sublingual and ranine vessels, and the buccal mucous membrane.

Dissection.—The Mylo-hyoid should now be removed, in order to expose the muscles which lie beneath; this is effected by reflecting it from its attachments to the hyoid bone and jaw, and separating it by a vertical incision from its fellow of the opposite side.

The **Genio-hyoid** is a narrow, slender muscle, situated immediately beneath[1] the inner border of the preceding. It arises from the inferior genial tubercle on the inner side of the symphysis of the jaw, and passes downward and backward, to be inserted into the anterior surface of the body of the os hyoides. This muscle lies in close contact with its fellow of the opposite side, and increases slightly in breadth as it descends.

Relations.—It is covered by the Mylo-hyoid, and lies along the lower border of the Genio-hyo-glossus.

Nerves.—The Digastric is supplied: its anterior belly, by the mylo-hyoid branch

[1] This refers to the depth of the muscles from the skin in the order of dissection. In the erect position of the body each of these muscles lies above the preceding.

of the inferior dental; its posterior belly, by the facial; the Stylo-hyoid, by the facial; the Mylo-hyoid, by the mylo-hyoid branch of the inferior dental; the Genio-hyoid, by the hypoglossal.

Actions.—This group of muscles performs two very important actions. They raise the hyoid bone, and with it the base of the tongue, during the act of deglutition; or, when the hyoid bone is fixed by its depressors and those of the larynx, they depress the lower jaw. During the first act of deglutition, when the mass is being driven from the mouth into the pharynx, the hyoid bone, and with it the tongue, is carried upward and forward by the anterior belly of the Digastric, the Mylo-hyoid, and Genio-hyoid muscles. In the second act, when the mass is passing through the pharynx, the direct elevation of the hyoid bone takes place by the combined action of all the muscles; and after the food has passed the hyoid bone is carried upward and backward by the posterior belly of the Digastric and Stylo-hyoid muscles, which assist in preventing the return of the morsel into the mouth.

4. Lingual Region.

Genio-hyo-glossus. Stylo-glossus.
Hyo-glossus. Palato-glossus.
Chondro-glossus.

Dissection.—After completing the dissection of the preceding muscles, saw through the lower jaw just external to the symphysis. Then draw the tongue forward, and attach it, by a stitch, to the nose; when its muscles, which are thus put on the stretch, may be examined.

The **Genio-hyo-glossus** has received its name from its triple attachment to the jaw, hyoid bone, and tongue, but it would be better named the *Genio-glossus*,

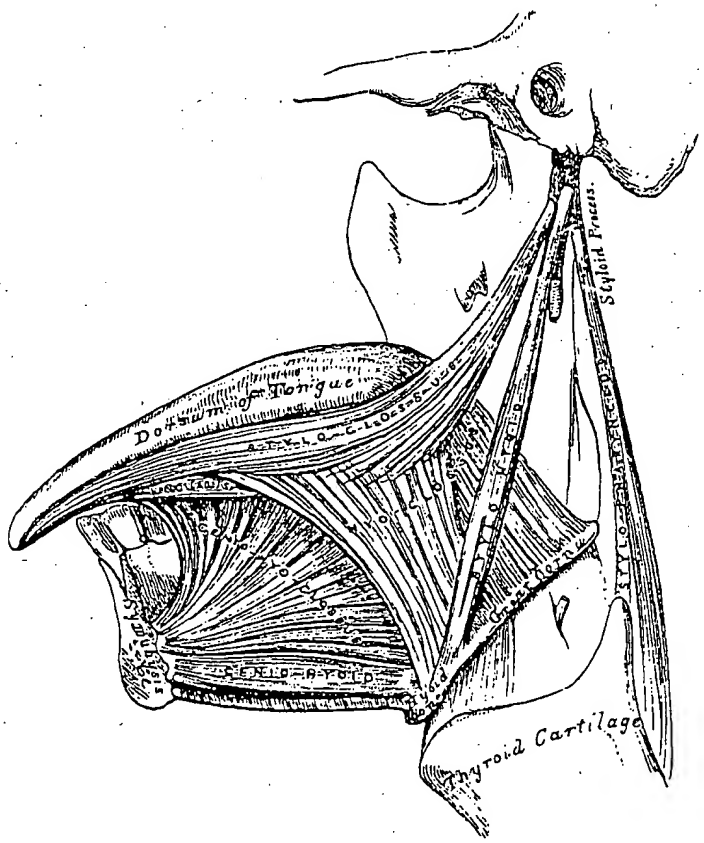

FIG. 204.—Muscles of the tongue. Left side.

since its attachment to the hyoid bone is very slight or altogether absent. It is a flat, triangular muscle, placed vertically on either side of the middle line, its apex

corresponding with its point of attachment to the lower jaw, its base with its insertion into the tongue and hyoid bone. It arises by a short tendon from the superior genial tubercle on the inner side of the symphysis of the jaw, immediately above the Genio-hyoid; from this point the muscle spreads out in a fan-like form, a few of the inferior fibres passing downward, to be attached by a thin aponeurosis into the upper part of the body of the hyoid bone, a few fibres passing between the Hyo-glossus and Chondro-glossus to blend with the Constrictor muscles of the pharynx; the middle fibres passing backward, and the superior ones upward and forward, to enter the whole length of the under surface of the tongue, from the base to the apex. The two muscles lie on either side of the median plane; behind, they are quite distinct from each other, and are separated at their insertion into the under surface of the tongue by a tendinous raphé, which extends through the middle of the organ; in front, the two muscles are more or less blended: distinct fasciculi are to be seen passing off from one muscle, crossing the middle line, and intersecting with bundles of fibres derived from the muscle on the other side (Fig. 205).

Relations.—By its *internal surface* it is in contact with its fellow of the opposite side; by its *external surface*, with the Inferior lingualis, the Hyo-glossus, the lingual artery and hypoglossal nerve, the lingual nerve, and sublingual gland; by its *upper border*, with the mucous membrane of the floor of the mouth (frænum linguæ); by its *lower border*, with the Genio-hyoid.

FIG. 205.—Muscles of the tongue from below. (From a preparation in the Museum of the Royal College of Surgeons of England.)

The **Hyo-glossus** is a thin, flat, quadrilateral muscle which arises from the side of the body and whole length of the greater cornu of the hyoid bone, and passes almost vertically upward to enter the side of the tongue, between the Stylo-glossus and Lingualis. Those fibres of this muscle which arise from the body are directed upward and backward, overlapping those arising from the greater cornu, which are directed upward and forward.

Relations.—By its *external surface*, with the Digastric, the Stylo-hyoid, Stylo-glossus, and Mylo-hyoid muscles, the submaxillary ganglion, the lingual and hypoglossal nerves, Wharton's duct, the ranine vein, the sublingual gland, and the deep portion of the submaxillary gland. By its *deep surface*, with the Stylo-hyoid ligament, the Genio-hyo-glossus, Lingualis, and Middle constrictor, the lingual vessels, and the glosso-pharyngeal nerve.

The **Chondro-glossus** is a distinct muscular slip, though it is sometimes described as a part of the Hyo-glossus, from which, however, it is separated by the fibres of the Genio-hyo-glossus, which pass to the side of the pharynx. It is about three-quarters to an inch in length, and arises from the inner side and base of the lesser cornu and contiguous portion of the body of the hyoid bone, and passes directly upward to blend with the intrinsic muscular fibres of the tongue, between the Hyo-glossus and Genio-hyo-glossus. A small slip of muscular fibre is occasionally found, arising from the cartilago triticia in the thyro-hyoid ligament, and passing upward and forward to enter the tongue with the hindermost fibres of the Hyo-glossus.

The **Stylo-glossus**, the shortest and smallest of the three styloid muscles, arises from the anterior and outer side of the styloid process, near its apex, and from the

stylo-mandibular ligament, to which its fibres, in most cases, are attached by a thin aponeurosis. Passing downward and forward between the internal and external carotid arteries, and becoming nearly horizontal in its direction, it divides upon the side of the tongue into two portions: one longitudinal, which enters the side of the tongue near its dorsal surface, blending with the fibres of the Lingualis in front of the Hyo-glossus; the other oblique, which overlaps the Hyo-glossus muscle and decussates with its fibres.

Relations.—By its *external surface*, from above downward, with the parotid gland, the Internal pterygoid muscle, the lingual nerve, and the mucous membrane of the mouth; by its *internal surface*, with the tonsil, the Superior constrictor, and the Hyo-glossus muscle.

The **Palato-glossus**, or **Constrictor isthmi faucium**, although it is one of the muscles of the tongue, serving to draw its base upward during the act of deglutition, is more nearly associated with the soft palate, both in its situation and function; it will consequently be described with that group of muscles.

Nerves.—The Palato-glossus is probably innervated by the spinal accessory nerve, through the pharyngeal plexus; the remaining muscles of this group, by the hypoglossal.

Muscular Substance of Tongue.—The muscular fibres of the tongue run in various directions. These fibres are divided into two sets—Extrinsic and Intrinsic. The extrinsic muscles of the tongue are those which have their origin external, and only their terminal fibres contained in the substance of the organ. They are: the Stylo-glossus, the Hyo-glossus, the Palato-glossus, the Genio-hyo-glossus, and part of the Superior constrictor of the pharynx (Pharyngeo-glossus). The intrinsic are those which are contained entirely within the tongue, and form the greater part of its muscular structure.

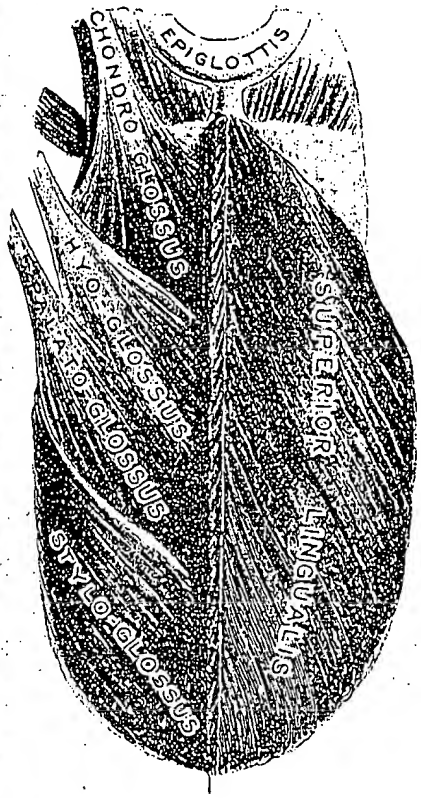

FIG. 206.—Muscles on the dorsum of the tongue.

The tongue consists of symmetrical halves separated from each other in the middle line by a fibrous septum. Each half is composed of muscular fibres arranged in various directions, containing much interposed fat, and supplied by vessels and nerves.

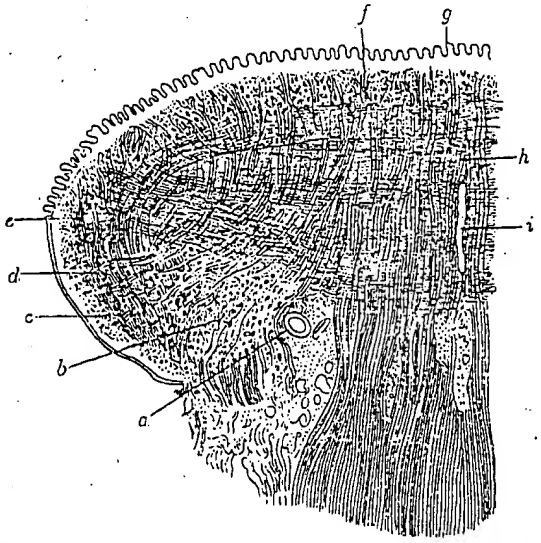

FIG. 207.—Coronal section of tongue. Showing intrinsic muscles. (Altered from Krause.) *a*, lingual artery; *b*, Inferior lingualis, cut through; *c*, fibres of Hyo-glossus; *d*, oblique fibres of Stylo-glossus; *e*, insertion of Transverse lingualis; *f*, Superior lingualis; *g*, papillæ to tongue; *h*, vertical fibres of Genio-hyo-glossus intersecting Transverse lingualis; *i*, septum.

To demonstrate the various fibres of the tongue, the organ should be subjected to prolonged boiling, in order to soften the connective tissue; the dis-

section may then be commenced from the dorsum (Fig. 206). Immediately beneath the mucous membrane is a submucous, fibrous layer, into which the muscular fibres which terminate on the surface of the tongue are inserted. Upon removing this, with the mucous membrane, the first stratum of muscular fibres is exposed. This belongs to the group of intrinsic muscles, and has been named the *Superior lingualis* (*m. longitudinalis superior*). It consists of a thin layer of oblique and longitudinal fibres which arise from the submucous fibrous layer, close to the Epiglottis, and from the fibrous septum, and pass forward and outward to the edges of the tongue. Between its fibres pass some vertical fibres derived from the Genio-hyo-glossus and from the vertical intrinsic muscle, which will be described later on. Beneath this layer is the second stratum of muscular fibres, derived principally from the extrinsic muscles. In front it is formed by the fibres derived from the Stylo-glossus, running along the side of the tongue, and sending one set of fibres over the dorsum which runs obliquely forward and inward to the middle line, and another set of fibres, seen at a later period of the dissection, on to the under surface of the sides of the anterior part of the tongue, which run forward and inward, between the fibres of the Hyo-glossus, to the middle line. Behind this layer of fibres, derived from the Stylo-glossus, are fibres derived from the Hyo-glossus, assisted by some few fibres of the Palato-glossus. The Hyo-glossus, entering the side of the under surface of the tongue, between the Stylo-glossus and Inferior lingualis, passes round its margin and spreads out into a layer on the dorsum, which occupies the middle third of the organ, and runs almost transversely inward to the septum. It is reinforced by some fibres from the Palato-glossus; other fibres of this muscle pass more deeply and intermingle with the next layer. The posterior part of the second layer of the muscular fibres of the tongue is derived from those fibres of the Hyo-glossus which arise from the lesser cornu of the hyoid bone, and are here described as a separate muscle—the Chondro-glossus. The fibres of this muscle are arranged in a fan-shaped manner, and spread out over the posterior third of the tongue. Beneath this layer is the great mass of the intrinsic muscles of the tongue, intersected at right angles by the terminal fibres of one of the extrinsic muscles—the Genio-hyo-glossus. This portion of the tongue is paler in color and softer in texture than that already described, and is sometimes designated the medullary portion in contradistinction to the firmer superficial part, which is termed the cortical portion. It consists largely of transverse fibres, the *Transverse lingualis* (*m. transversus linguæ*), and of vertical fibres, the *Vertical lingualis* (*m. verticulis linguæ*). The Transverse lingualis forms the largest portion of the third layer of muscular fibres of the tongue. The fibres arise from the median septum, and pass outward to be inserted into the submucous fibrous layer at the sides of the tongue. Intermingled with these transverse intrinsic fibres are transverse extrinsic fibres derived from the Palato-glossus and the Superior constrictor of the pharynx. These transverse extrinsic fibres, however, run in the opposite direction, passing inward toward the septum. Intersecting the transverse fibres are a large number of vertical fibres derived partly from the Genio-hyo-glossus and partly from intrinsic fibres, the Vertical lingualis. The fibres derived from the Genio-hyo-glossus enter the under surface of the tongue on each side of the median septum from base to apex. They ascend in a radiating manner to the dorsum, being inserted into the submucous fibrous layer covering the tongue on each side of the middle line. The Vertical lingualis is found only at the borders of the fore part of the tongue, external to the fibres of the Genio-hyo-glossus. Its fibres extend from the upper to the under surface of the organ, decussating with the fibres of the other muscles, and especially with the Transverse lingualis. The fourth layer of muscular fibres of the tongue consists partly of extrinsic fibres derived from the Stylo-glossus, and partly of intrinsic fibres, the *Inferior lingualis* (*m. longitudinalis inferior*). At the sides of the under surface of the organ are some fibres derived from the Stylo-glossus, which, as it runs forward at the side of the tongue, gives off fibres which, passing forward and inward between the fibres of the Hyo-glossus, form an inferior oblique stratum which joins in front with the

anterior fibres of the Inferior lingualis. The Inferior lingualis is a longitudinal band, situated on the under surface of the tongue, and extending from the base to the apex of the organ. Behind, some of its fibres are connected with the body of the hyoid bone. It lies between the Hyo-glossus and the Genio-hyo-glossus, and in front of the Hyo-glossus it gets into relation with the Stylo-glossus, with the fibres of which it blends. It is in relation by its under surface with the ranine artery.

Surgical Anatomy.—The fibrous septum which exists between the two halves of the tongue is very complete, so that the anastomosis between the two lingual arteries is not very free, a fact often illustrated by injecting one-half of the tongue with colored size, while the other half is left uninjected or is injected with size of a different color.

This is a point of considerable importance in connection with removal of one-half of the tongue for cancer, an operation which is now frequently resorted to when the disease is strictly confined to one side of the tongue. If the mucous membrane is divided longitudinally exactly in the middle line, the tongue can be split into halves along the median raphe without any appreciable hæmorrhage, and the diseased half can then be removed.

Actions.—The movements of the tongue, although numerous and complicated, may be understood by carefully considering the direction of the fibres of its muscles. The *Genio-hyo-glossi* muscles, by means of their posterior fibres, draw the base of the tongue forward, so as to protrude the apex from the mouth. The anterior fibres draw the tongue back into the mouth. The whole length of these two muscles, acting along the middle line of the tongue, draw it downward, so as to make it concave from side to side, forming a channel along which fluids may pass toward the pharynx, as in sucking. The *Hyo-glossi* muscles depress the tongue and draw down its sides, so as to render it convex from side to side. The *Stylo-glossi* muscles draw the tongue upward and backward. The *Palato-glossi* muscles draw the base of the tongue upward. With regard to the intrinsic muscles, both the Superior and Inferior linguales tend to shorten the tongue, but the former, in addition, turn the tip and sides upward so as to render the dorsum concave, while the latter pull the tip downward and cause the dorsum to become convex. The Transverse lingualis narrows and elongates the tongue, and the Vertical lingualis flattens and broadens it. The complex arrangement of the muscular fibres of the tongue, and the various directions in which they run, give to this organ the power of assuming the various forms necessary for the enunciation of the different consonantal sounds; and Dr. Macalister states that "there is reason to believe that the musculature of the tongue varies in different races owing to the hereditary practice and habitual use of certain motions required for enunciating the several vernacular languages."

5. Pharyngeal Region.

Inferior constrictor.	Superior constrictor.
Middle constrictor.	Stylo-pharyngeus.
Palato-pharyngeus. }	(See next section.)
Salpingo-pharyngeus. }	

Dissection (Fig. 208).—In order to examine the muscles of the pharynx, cut through the trachea and œsophagus just above the sternum, and draw them upward by dividing the loose areolar tissue connecting the pharynx with the front of the vertebral column. The parts being drawn well forward, apply the edge of the saw immediately behind the styloid processes, and saw the base of the skull through from below upward. The pharynx and mouth should then be stuffed with tow, in order to distend its cavity and render the muscles tense and easier of dissection.

The **Inferior constrictor**, the most superficial and thickest of the three constrictors, arises from the sides of the cricoid and thyroid cartilages. To the cricoid cartilage it is attached in the interval between the Crico-thyroid muscle in front and the articular facet for the thyroid cartilage behind. To the thyroid cartilage it is attached to the oblique line on the side of the great ala, the cartilaginous surface behind it, nearly as far as its posterior border, and to the inferior cornu. From these attachments the fibres spread backward and inward, to be inserted into the fibrous raphe in the posterior median line of the pharynx.

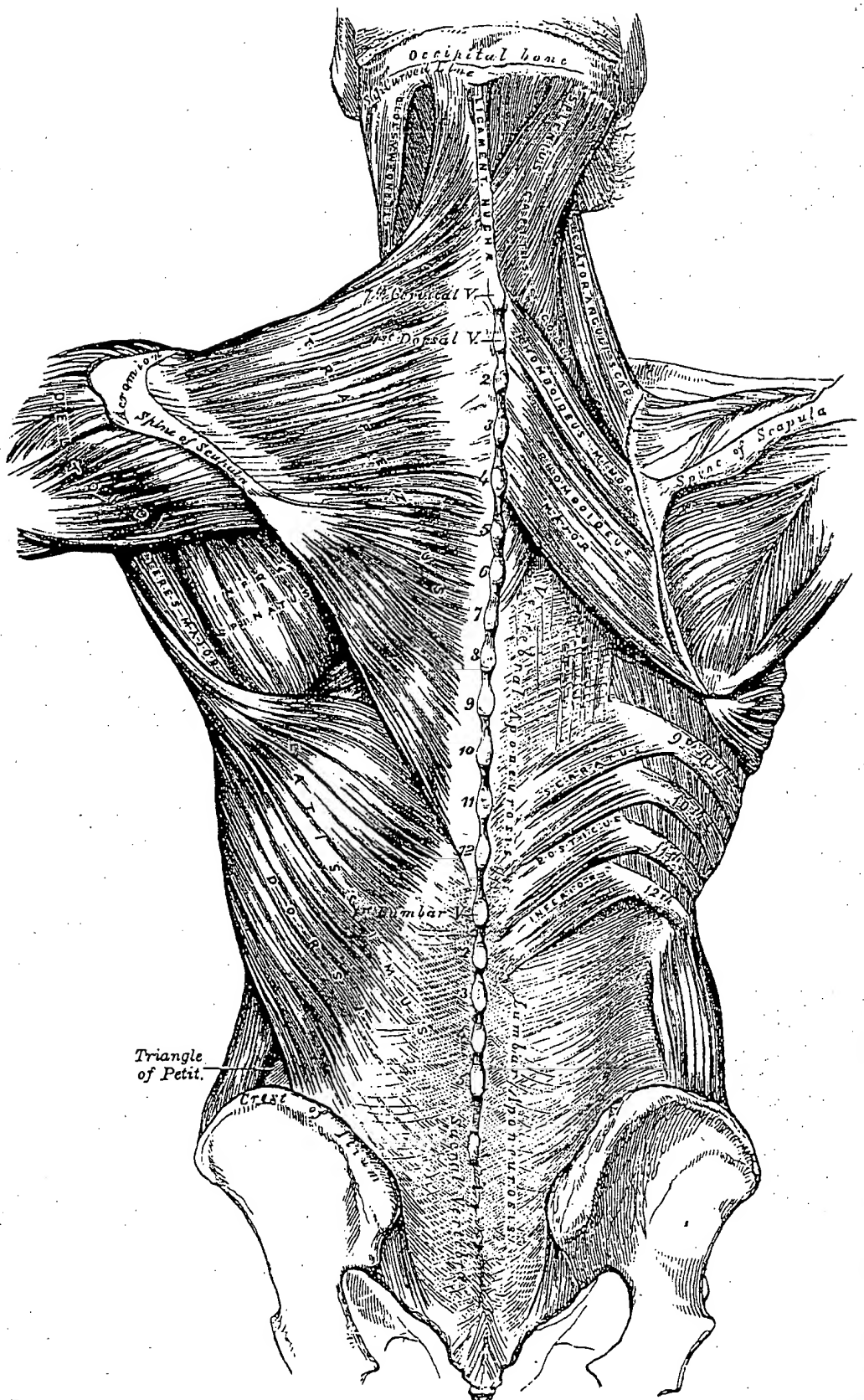

FIG. 213.—Muscles of the back. On the left side is exposed the first layer; on the right side, the second layer and part of the third.

Relations.—By its *superficial surface*, with the integument; by its *deep surface*, in the neck, with the Complexus, Splenius, Levator anguli scapulæ, and